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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,079	10/07/2003	Kwan-Ho Chan	CHAN-33 CON	9937

44270 7590 12/22/2010
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EXAMINER	
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ART UNIT	PAPER NUMBER
3773	

NOTIFICATION DATE	DELIVERY MODE
12/22/2010	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STRYKER ENDOSCOPY

Appeal 2009-010003
Application 10/680,079
Technology Center 3700

Before RICHARD E. SCHAFER, JAMESON LEE, and
RICHARD TORCZON, *Administrative Patent Judges*.

LEE, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

A. STATEMENT OF THE CASE

The real party in interest, Stryker Endoscopy ("Stryker"), appeals under 35 U.S.C. § 134(a) from a rejection of claims 31, 32, 36, 38, and 39. We have jurisdiction under 35 U.S.C. § 6(b). We *affirm*.

References Relied on by the Examiner

Violante	3,840,017	Oct. 8, 1974
Goldrath	5,330,488	Jul. 19, 1994
Burkhart et al. ("Burkhart")	5,681,333	Oct. 28, 1997

The Rejections on Appeal

The Examiner rejected claim 36 under 35 U.S.C. § 102(b) as anticipated by Violante.

The Examiner rejected claims 31, 38, and 39 under 35 U.S.C. § 103(a) as unpatentable over Violante and Burkhart.

The Examiner rejected claim 32 under 35 U.S.C. § 103(a) as unpatentable over Violante, Burkhart, and Goldrath.

The Invention

The invention relates to a surgical device for use in surgical procedures such as the repair of torn menisci. (Spec. 9:2-6.) The device operates to deliver suture to and retrieve suture from the interior of a body. Claim 36 is reproduced below (App. Br. 15 Claims App'x.):

> 36. A surgical apparatus for delivering and retrieving suture, the apparatus comprising:
>
> a cannula having a distal end, a proximal end, and a lumen extending therebetween; and

a handle having a distal end, a proximal end, a passageway extending through at least a portion of said handle, and an exposed surface disposed between the passageway and the distal end of said handle;

wherein the proximal end of said cannula is attached to said handle, with the lumen of said cannula being in communication with the exposed surface of said handle;

wherein the exposed surface is adapted to support a suture extending through said handle such that the suture is manually engageable by an operator for freely moving the suture selectively in the direction of the handle distal end and in the direction of the handle proximal end;

wherein said passageway is provided with an opening at the handle proximal end, and wherein the opening is positioned to permit the suture to be fed into the opening along a pathway parallel to the lumen;

wherein at least a portion of the distal end of said cannula is configured to drive a suture against tissue without severing the suture.

B. ISSUES

1. Did the Examiner incorrectly find that Violante discloses a surgical apparatus which includes a cannula that "is configured to drive a suture against tissue without severing the suture" as recited in claim 36?

2. Did the Examiner incorrectly determine that the combination of Violante and Burkhart teaches a passer and a puller assembly as recited in claim 38?

3. Did the Examiner incorrectly determine that in view of the combined teachings of Violante and Burkhart one with ordinary skill in the art would have recognized that suture material and a puller assembly may be

manually engaged by an operator at a planar portion located on a handle of a passer assembly?

4. Did the Examiner incorrectly determine that the subject matter of claim 32, including the feature of a "hook retriever" for retrieving suture, would have been obvious in view of the teachings of Violante, Burkhart, and Goldrath?

C. PRINCIPLES OF LAW

Anticipation is established when a single prior art reference discloses all elements of the claimed invention. *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990).

It is improper to read unclaimed features from particular embodiments or examples given in the specification into the claims. *Constant v. Advanced Micro-Devices, Inc.* 848 F.2d 1560, 1571 (Fed. Cir. 1988).

During examination, claim terms are given their broadest reasonable interpretation consistent with the specification. *In re Prater*, 415 F.2d 1393, 1404 (CCPA 1969).

The broadest reasonable interpretation rule recognizes that before a patent is granted the claims are readily amended as a part of the examination process and that an applicant has the opportunity and responsibility to remove any ambiguity in claim meaning by making an amendment. *In re Bigio*, 381 F.3d 1320, 1324 (Fed. Cir. 2004).

In an obviousness analysis, it is not necessary that the device of one reference must, without change, be physically insertable into the device of another. *In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983); *In re Keller*, 642 F.2d 413, 425 (Fed. Cir. 1981). The test for obviousness is what the

combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller*, 642 F.2d at 425.

A basis to combine teachings need not be expressly stated in any prior art reference. *In re Kahn*, 441 F.3d 977, 987 (Fed. Cir. 2006). There need only be an articulated reasoning with rational underpinnings to support a motivation to combine teachings. *Id.* at 988.

A prior art reference is enabling for a claimed invention if the reference enables a person of ordinary skill in the art to make the invention without undue experimentation. *Impax Laboratories Inc. v. Aventis Pharmaceuticals Inc.*, 545 F.3d 1312, 1314 (Fed. Cir. 2008).

D. FINDINGS AND ANALYSIS

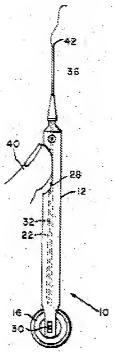
The Examiner rejected (1) claim 36 as anticipated by Violante, (2) claims 31, 38, and 39 as unpatentable over Violante and Burkhart, and (3) claim 32 as unpatentable over Violante, Burkhart, and Goldrath.

Anticipation

Claim 36 is directed to a surgical apparatus for delivering and retrieving suture where the apparatus includes a cannula, *i.e.*, a hollow tube for insertion into a body cavity. The dispute centers on the requirement that a portion of a distal end of the cannula is "configured to drive a suture against tissue without severing the suture."

The Examiner relied on Violante as disclosing the above-noted feature of claims 36. Violante's Figure 2 is reproduced on the right. As shown in the figure, Violante discloses a surgical instrument 10 including a hollow suture needle 20 (unnumbered in Figure 2) for delivering suture thread to a desired location within a body. (Violante 2:16-22.) The end of needle 20 includes a tip 42 described as "beveled and sharpened." (*Id.* at 2:28.) Violante also describes that the tip presents a sharpened edge that may be employed in cutting of suture material. (*Id.* at 2:30-31.)

FIG. 2



Stryker contends that Violante does not show all the elements of claim 36. Stryker submits that embodiments of its invention which incorporate the pertinent feature of claim 36 are illustrated in its Figures 42 and 43 and described in its specification. In particular, according to Stryker, in those embodiments a portion of its cannula is "preferably blunted or rounded off" forming a "blunt heel." (App. Br. 5:12-6:2.) Stryker argues that Violante's description of its tip as being "beveled and sharpened" and which may be used for the cutting of suture material means that the tip does not include a "blunt heel." (*Id.* at 6:13-16.)

Stryker's argument is misplaced. Claim 36 does not require a "blunt heel." That some disclosed embodiments of Stryker's invention describe a "blunt heel" as an example of a structure that may "drive a suture against tissue without severing the suture" is of no moment. Those exemplary embodiments do not establish a limiting definition for the claim term. It is improper to read unclaimed features from particular embodiments or

examples given in the specification into the claims. *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d at 1571. Rather, during examination, claim terms are given their broadest reasonable interpretation consistent with the specification. *In re Prater*, 415 F.2d at 1404. The broadest reasonable interpretation rule recognizes that before a patent is granted the claims are readily amended as a part of the examination process and that an applicant has the opportunity and responsibility to remove any ambiguity in claim meaning by making an amendment. *In re Bigio*, 381 F.3d at 1324.

In this case, if Stryker intended that its cannula end includes the specific structural characteristic of a "blunt heel," it could easily have amended the claims accordingly. It did not. Claim 36 requires simply that "a portion of the distal end of said cannula is configured to drive a suture against tissue without severing the suture." That feature is met in the prior art by a cannula or tube having a distal end with any portion of the distal end configured such that it does not sever suture when driven against tissue.

Violante's element 14 is shown and described as a cylindrical hollow needle, *i.e.*, a tube, which delivers suture thread to a body cavity. (Violante 2:16-35; Figs. 1 & 2.) The distal end of the tube has a tip 42 that is "beveled" forming a slanted face on one side of the tip. The Examiner reasoned that even if the beveled portion of Violante's tip is sharpened, other portions of the tip would be incapable of severing suture. We agree with the Examiner. The side of Violante's tip that is not beveled remains unmodified and thus retains the curved shape of the cylindrical tube's outer surface. The curved outer surface of the tube, including the unaltered curved portion of the tip, is not used for cutting suture. Stryker does not explain why that

curved portion of Violante's tip does not form a component that would not operate to sever suture when driven against tissue.

In any event, we note in the alternative that Stryker's claim 36, as broadly written, excludes only those structures that would sever a suture in every instance upon being driven against tissue. That a "beveled and sharpened tip" includes a sharpened edge which may be useful in cutting a suture material does not mean that in all circumstances the tip severs the suture material. Indeed, the tip's ability to cut the material is not dependent solely on the tip's configuration but is also a function of other factors such as the driving force applied to the suture, the strength of the material that makes up the suture, and the tension on the suture. Violante's tip, even if sharpened, may be driven against tissue with a force of inadequate magnitude to severe a particular suture. It is neither unreasonable nor inconsistent with Stryker's specification that the beveled and sharpened tip in Violante constitutes a structure that in some circumstances will not sever a suture when pressed or driven against body tissue. That is sufficient to satisfy claim 36.

For the foregoing reasons, we sustain the rejection of claim 36 as anticipated by Violante.

Obviousness

The Examiner rejected claims 31, 38, and 39 as unpatentable over Violante and Burkhart, and claim 32 as unpatentable over Violante, Burkhart, and Goldrath. Stryker argues each of claims 38, 39, and 32 separately. Claim 31 is dependent on claim 39. Stryker does not argue the patentability of claim 31 apart from claim 39.

Claim 38

Claim 38 is independent and is drawn to a surgical apparatus for delivering and retrieving suture. The apparatus includes a "passer assembly" and a "puller assembly." A "passer assembly" is a component that allows for the delivery and positioning of suture material at a desired location within a body. A "puller assembly" provides for the removal of suture material.

The Examiner determined that Violante discloses a passer assembly as required by claim 38 but lacks disclosure of a puller assembly. (Ans. 3:21-4:7.) To make up for the deficiency, the Examiner relied on the teachings of Burkhart. Burkhart discloses a surgical device for the insertion and removal of suture during an arthroscopic procedure. (Burkhart Abstract.) The Examiner pointed to Burkhart's element 50 as forming a passer assembly and element 66 as forming a puller assembly. (Ans. 4:7-9.) Element 50 is disclosed as a "suture passer" and operates to position suture material within a body. (Burkhart 4:53-58.) Suture passer 50 is a passer assembly. Element 66 is described as a "flexible wire loop" and includes a flexible rod 68 and a closed loop 70 attached to the distal end of the rod. (*Id.* at 5:5-10.) Loop 70 operates to grasp suture material and allows for the material to be transported through a lumen or tube of suture passer 50. (*Id.* at 5:10-15.) The Examiner reasonably determined, and Stryker does not dispute, that Burkhart's flexible wire loop 66 constitutes the "puller assembly" of claim 38.

Rather, in challenging the Examiner's rejection, Stryker first contends that the teachings of Violante and Burkart may not physically be combined. (App. Br. 7:3-6.) Stryker attempts to makes its case by visually comparing

Burkhart's Figures 6 and 7 to Violante's Figures 1-3 and opines that Burkhart's tube 52 which receives flexible wire loop 66 appears to be a larger cannula than Violante's hollow needle 20. (App. Br. 7:9-12.) Based on that comparison, Stryker concludes that Violante's hollow needle 20 is too small to receive Burkhart's wire loop 66. Stryker also contends that if Burkhart's wire loop 66 were inserted into Violante's hollow needle 20, then handle 72 of the wire loop would protrude from Violate's device so as to be "inconvenient" for a surgeon. (*Id.* at 7:14-22.)

Stryker's contentions are misplaced. At the outset, Stryker does not offer any objective evidence, such as expert testimony, to support its contentions. The figures of Violante and Burkhart are not engineering blueprints. Those figures are simply illustrations of embodiments of each invention and do not establish limiting dimensions for the devices depicted. Merely comparing those illustrations with one another does not establish that one with ordinary skill in the art would have viewed the inventions of Violante and Burkhart as somehow inappositely sized so as to preclude their combination.

Furthermore, the assertion that a surgeon would regard the combination of Violante and Burkhart as producing an "inconvenient" device is unsubstantiated attorney argument lacking any evidentiary basis. Argument of counsel cannot take the place of evidence lacking in the record. *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 595 (Fed. Cir. 1997);

Moreover, in evaluating obviousness, it is not necessary that the device of one reference must, without change, be physically insertable into the device of another. *In re Sneed*, 710 F.2d at 1550; *In re Keller*, 642 F.2d at 425. Nor does combining the teachings of references require that all, or

even any, of the particular characteristics of each reference, such as a component's size, must be preserved. The test for obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller*, 642 F.2d at 425.

Here, one with ordinary skill in the art would have appreciated from the teachings of Violante and Burkhart that in the surgical apparatus art, a hollow tube used for delivering suture thread may also receive a device for retrieving the suture thread. One with ordinary skill in the art possesses ordinary creativity and is not an automaton. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). That some variation in component sizing may be necessary for one of ordinary skill to implement the teachings of Burkhart onto Violante does not render their teachings not combinable. We reject Stryker's argument to the contrary.

Stryker also argues that even if Violante and Burkhart could be combined there is no motivation for the combination. (App. Br. 7:3-6.) Stryker's argument is unpersuasive.

Violante and Burkhart each discloses a passer assembly for passing suture material to a location within a body. Burkhart discloses that a puller assembly may also be used with a passer assembly for removing suture material. The Examiner reasoned that in view of the teachings of the prior art one with ordinary skill in the art would have appreciated that Violante's passer assembly for placing suture material would also desirably incorporate a puller assembly, such as Burkhart's wire loop, for removing suture material. (Ans. 4:15-20.) A basis to combine teachings need not be expressly stated in any prior art reference. *In re Kahn*, 441 F.3d at 987.

There need only be an articulated reasoning with rational underpinnings to support a motivation to combine teachings. *Id.* at 988.

Here, the Examiner's reasoning for combining the teachings of Violante and Burkhart is rational. A person of ordinary skill and creativity would have readily recognized that one device for passing suture material to a tissue within a body, such as in Violante, would benefit from a puller device for subsequently removing the suture material, as is disclosed in Burkhart. We reject Stryker's assertion that one with ordinary skill in the art would not have had adequate motivation to combine the teachings of Violante and Burkhart.

For the foregoing reasons, we sustain the rejection of claim 38 over Violante and Burkhart.

Claims 31 and 39

Claim 39 is dependent on claim 38. Claim 31 is in turn dependent on claim 39. Claim 31 is argued together with claim 39. Claim 38 includes the features of a puller assembly and a passer assembly with a handle having a body. The body includes a recess which defines a "planar surface." (App. Br. 15 Claims App'x.) Claim 39 adds limitations concerning the function of the planar surface in allowing for manipulation of both suture material and the puller assembly. Claim 39 is reproduced below (App. Br. 16 Claims App'x.):

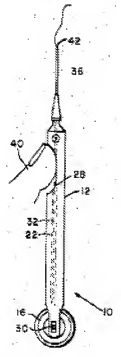
> 39. The surgical apparatus in accordance with claim 38 wherein the planar surface is adapted to support a selected one of a suture extending through said handle and said puller assembly shaft extending through said handle, such that the suture and said puller assembly shaft are each manually engageable by an operator for moving the suture and said puller assembly shaft selectively in the direction of the nose portion and the cannula, and in the direction of

> the body proximal end portion for rearward movement of the puller assembly and suture out the axially disposed passageway at the proximal end of the body.

Thus, claim 39 requires that the planar surface supports either suture material or the puller assembly and enables an operator to manually manipulate each of those components at the planar surface. Stryker generally argues that the Examiner has not explained how the combined teachings of Violante and Burkhart describe a planar surface where each of the suture material and a puller assembly may be operated. (App. Br. 10:4-11.)

We are unpersuaded by Stryker's argument. Violante discloses a surgical device 10 as a suture passer assembly including a handle with a body portion 12 and a recess 28 in the body portion. As illustrated in Violante's Figure 2 (reproduced on the right), Violante discloses that suture material 32 is manipulated by a thumb 40 that may access the suture material at a planar surface formed by recess 28. (Violante 2:16-26.) Violante does not disclose a puller assembly. However, as discussed above, Burkhart discloses that a puller assembly may be used in conjunction with a passer assembly. In Burkhart, flexible wire loop 66, *i.e.*, a puller assembly, is directed through the handle of suture passer 50. Although Burkhart does not disclose a planar surface for manipulating the puller assembly, one with ordinary skill and creativity in the art would have appreciated from the combined teachings of Violante and Burkhart that

FIG. 2



components which are directed through the handle of a passer assembly, such as either suture material or a puller assembly, may be operated at a planar portion formed within the handle, such as that formed by Violante's recess 28.

Stryker has not shown that the Examiner's rejection of claims 31 and 39 is improper. We sustain the rejection of claim 31 and 39 over Violante and Burkhart.

Claim 32

Claim 32 is dependent on claims 39 and requires that the puller assembly is specifically a "hook retriever." The Examiner determined that Burkhart's puller assembly is formed as a loop and not as a hook retriever. To account for a hook retriever, the Examiner relied on Goldrath.

Goldrath discloses a suturing kit that includes a "trocar" 30 which operates as a hollow guide structure for a snare 32 to grasp suture material within a body. (Goldrath 5:27-41.) Goldrath describes that snare 32 may be formed as a loop or may have another configuration such as a hook for capturing the free end of suture material. (*Id.* at 5:42-48.) The Examiner determined that Goldrath's disclosure of a hook constitutes the "hook retriever" recited in claim 32. In view of Goldrath's teachings, the Examiner reasoned that one with ordinary skill in the art would have recognized that a hook retriever is a known and viable alternative to the loop structure shown in Burkhart for gasping suture material. (Ans. 5:2-10.)

Stryker contends that Goldrath's disclosure is so "brief" as to not present an enabling disclosure for the hook retriever that is required by claim 32. (App. Br. 11:12-16.)

We reject Stryker's contention. A prior art reference is enabling for a claimed invention if the reference enables a person of ordinary skill in the art to make the invention without undue experimentation. *Impax Laboratories Inc.*, 545 F.3d at 1314. Here, Goldrath teaches that loop structures and hook structures are alternative configurations for a snare that is passed through a tube and perform the same function in snaring suture material. The implementation of one known snaring structure, such as a hook, in place of another known snaring structure, such as a loop, is not the product of undue experimentation and instead involves merely routine design considerations readily addressed by one with ordinary skill in the art. Stryker has not submitted declaration evidence to demonstrate otherwise. Also, that Goldrath shows no need for a more detailed disclosure of its hook retriever suggests that the device is so simple and its implementation so routine as to render unnecessary any further description.

On this record, we are unpersuaded that Goldrath is non-enabling for the hook retriever recited in claim 32. We sustain the rejection of claim 32 as unpatentable over Violante, Burkhart, and Goldrath.

E. CONCLUSION

1. The Examiner did not incorrectly determine that Violante discloses a surgical apparatus which includes a cannula that "is configured to drive a suture against tissue without severing the suture" as recited in claim 36.

2. The Examiner did not incorrectly determine that the combination of Violante and Burkhart teaches a passer and a puller assembly as recited in claim 38.

3. The Examiner did not incorrectly determine that in view of the combined teachings of Violante and Burkhart one with ordinary skill in the art would have recognized that suture material and a puller assembly may be manually engaged by an operator at a planar portion located on a handle of a passer assembly.

4. The Examiner did not incorrectly determine that the subject matter of claim 32, including the feature of a "hook retriever" for retrieving suture, would have been obvious in view of the teachings of Violante, Burkhart, and Goldrath.

F. ORDER

The rejection of claim 36 under 35 U.S.C. § 102(b) as anticipated by Violante is affirmed.

The rejection of claims 31, 38, and 39 under 35 U.S.C. § 103(a) as unpatentable over Violante and Burkhart is affirmed.

The rejection of claim 32 under 35 U.S.C. § 103(a) as unpatentable over Violante, Burkhart, and Goldrath is affirmed.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

Appeal 2009-010003
Application 10/680,079

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